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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/476,689	12/30/1999	KENT C.B. STALKER	ACS-52008(18	8160

24201 7590 06/05/2007
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EXAMINER

GRAY, PHILLIP A

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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06/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/476,689	Applicant(s) STALKER, KENT C.B.	
	Examiner Phillip Gray	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's communication of 3/28/2007.

Currently amended claims 23-44 are pending and rejected below.

Response to Arguments and Amendments

Applicant's arguments filed 3/28/2007 have been fully considered but they are not persuasive. Applicant argues that the addition of claim language "a directional member attached to the filtering member for directing body fluid and emboli into the filter member, the directional member being made from a pliable material having properties of blocking the passage of the fluid and the emboli and being expandable by the fluid flow in the body vessel to form a truncated conical shape when placed in an expanded position" distinguishes the applicants invention over the prior art of record, (Gilson).

It is examiners position that Gilson does disclose a directional member made of a pliable material and being expandable to form a truncated conical shape when in an expanded position, and further is fully capable of the functional operational limitations of directing body fluid into the filter member, blocking the passage and expandable by fluid flow. Examiner is of the position that the directional and filtering members (see rejection below) are made of a pliable material since they must navigate the body passage and are stored/carried in a flexible catheter structure. Further it is Examiners position that the directional and filtering members are in a "truncated conical shape", as shown in figures 40, 19C, and figures 14 and 15 (directional members 30 and filter element 31), Gilson shows that the directional member/filter element would have a "truncated conical

shape” when in an expanded position. It is also examiners position that the Gilson directional member would block the passage of fluid and would be expanded by fluid flow (see figures 1, 8, 9, 10, and 18), and also described in paragraphs beginning at column 5 line 32.

Given this analysis of the claims and limitations, as described in the rejection below, the elements of Gilson are fully capable of satisfying the claimed limitations as currently written. The Gilson elements are fully capable of satisfying all structural, operational, functional, and spatial limitations as written in the claims. Therefore the rejections stand and are proper.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

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directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 23-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Gilson et al. (U.S. Patent Number 6,336,934). Gilson discloses an embolic protection device having a collapsible filter element (105) mounted on the end of a catheter (118) and optionally mounted on a tubular sleeve (104).

Concerning 23, 27, and 36, Gilson discloses an embolic filtering catheter apparatus containing a filtering portion (105), with directional member (50) being made from a pliable material, with no self-expanding properties, expandable by the fluid flow in the body vessel (see column 5, paragraphs at lines 30-40). When directional member is in elongated state, disposed against the vessel wall, the member directs blood, fluid and emboli into the relatively disposed filter member (see paragraphs at column 15, lines 24-41).

Concerning claims 23-24 and 29-30, the filtering member device is made from blood filtering material and braided/woven biocompatible material which is capable of blocking the passage of an emboli, and is expandable by the expansion of the directional member (see paragraph at column 15, lines 9-30). The expanded filtering directional device is a truncated conical shape (see column 14, lines 60-62, figures 37 and 39), that directs fluid into the filtering member (105).

Concerning claims 25, 26, 31, 35, 37-39, and 44, Gilson discloses an embolic protection catheter device that contains an elongate tubing lumen with a slide-able shaft member adaptable to allow an interventional device to be advanced into position within a body vessel (as in figures 13-18). The filtering portion and member are disposed within the elongate tubing lumen in a compacted delivery position. These interventional devices may be advanced over the outer or inner surfaces of the elongate tubing lumen or inner sheath (as in figures 13-18 and 28-37). A shaft member (guide wire 101), contacting the interior of the filter member, is movable within the lumen for delivery and retrieval of the filtering means from the elongate shaft, is also disclosed in Gilson. Gilson further discloses a sheath/sleeve (104) means for retracting the filtering means back into the lumen.

Concerning claim 28, 32-34, and 40-43, the Gilson embolic filter device discloses a plurality of restraining wires (30) attached to the filter mesh (31) and directional member (34) from within the elongate lumen (35), which can retract the filter and directional member to the collapsed position and into a recovery sheath or sleeve (104 or 32), via a location outside the body vessel (figures 11-15). These wires are held in a collapsed position during delivery of the filter member. The plurality of wires extend outward and may hold the filter open while the filter is deployed. (See paragraphs at column 10, line 55 through column 11, line 33)

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PhA

PAG

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5/29/07